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Statement for the Record

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INTRODUCTION

Good afternoon, Chairman Davis, Congressman Waxman, and distinguished members of the Committee. I am pleased to appear before you today to discuss the role of the Department of Homeland Security (DHS) in implementing Project BioShield and our close coordination with the Department of Health and Human Services throughout this process.

Before focusing on the Department's specific activities in support of Project Bioshield, I would like to put these activities in the broader context of the overall responsibilities and activities of the DHS Biological Countermeasures Portfolio (Bio Portfolio) which I direct. The mission of this Portfolio is to provide the understanding, technologies, and systems needed to anticipate, deter, protect against, detect, mitigate, and recover from possible biological attacks on this nation's population, agriculture or infrastructure.

In addressing this mission, DHS has a leadership role in several key areas, and a partnership role in others. Those areas in which the Science and Technology (S&T) Directorate has a significant leadership role are in:

- Providing an overall end-to-end understanding of an integrated biodefense strategy, so as to guide the Secretary and the rest of the Department in its responsibility to coordinate the nation's efforts to deter, detect, and respond to acts of biological terrorism.

- Providing scientific support to understand better both current and future biological threats and their potential impacts so as to guide the research and development of biodefense countermeasures such as vaccines, drugs, detection systems and decontamination technologies.

- Developing early warning, detection and characterization systems to permit timely response to mitigate the consequence of a biological attack.

- Conducting technical forensics to analyze and interpret materials recovered from an attack to support attribution.

- Operation of the Plum Island Animal Disease Center to support both research and development (R&D) and operational response to foreign animal diseases such as foot and mouth disease.

DHS also supports our partnering departments and agencies with their leads in other key areas of an integrated biodefense: the Department of Health and Human Services (HHS) on medical countermeasures and mass casualty response; the Department of Defense (DoD) on broad range of homeland security/homeland defense issues; the U.S. Department of Agriculture (USDA) on agriculture biosecurity; USDA and HHS on food defense; the Department of Veterans' Affairs (VA) on maintaining pharmaceutical caches (antidotes, vaccines and ventilators); the Environmental Protection Agency (EPA) on

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decontamination and on water safety; the Department of Justice on bioterrorism investigations; and the Intelligence Community on threat warnings.

Today I would like to focus on those aspects of our work that play a major role in BioShield implementation. I will begin with a description of the coordination between DHS and HHS on the near-term implementation of the BioShield Program and then move on to three major activities to support and guide future BioShield acquisitions: risk assessments across a broader set of biological agents; a strategy for addressing the engineered threat; and scientific research to reduce key uncertainties in these risk assessments. In the course of these discussions, I will also address the specific questions that the Committee raised in their invitation letter to this hearing.

COORDINATION BETWEEN DHS AND HHS ON NEAR-TERM IMPLEMENTATION OF THE BIOSHIELD PROGRAM

The Project BioShield Act of 2004 charges the Secretary of Homeland Security with the responsibility to determine which biological, chemical, radiological or nuclear threats constitute a Material Threat to our Nation's security. To fulfill this responsibility, the DHS Science and Technology Directorate, in partnership with our Information Analysis and Infrastructure Protection Directorate, has been conducting formal threat assessments of the agents of greatest concern to establish plausible high consequence scenarios. These assessments combine intelligence information with technical assessments of the feasibility of a terrorist to produce and disseminate the agent to provide an indication of the number of exposed individuals, the geographical extent of the exposure, and other collateral effects. If these consequences are of such a magnitude to be of significant concern to our national security or public health, the Secretary of DHS then issues a formal Material Threat Determination to the Secretary of HHS, which initiates the BioShield process. Subsequently, HHS, assisted by the interagency Weapons of Mass Destruction Medical Countermeasures subcommittee, determines the need for, and requirements of, any new medical countermeasures. Any recommendations issued for the acquisition of a specific countermeasure are evaluated through an interagency process and form the basis of the U.S. Government requirements. After approval of these requirements by the Office of Management and Budget, HHS issues a Request for Proposals and implements and manages the subsequent acquisition process through delivery of the countermeasures to the Strategic National Stockpile.

As described above, the normal process is to have an in depth threat and risk assessment precede the Material Threat Determination. However, four threats were recognized to be of such urgency, that the Secretary of DHS issued Material Threat Determinations for them soon after the enactment of BioShield legislation and concurrently initiated in depth assessments of plausible high consequence scenarios to better inform procurement requirements. These four threats are anthrax, smallpox, botulinum toxin, and radiological/nuclear devices. Subsequently, full assessments have been performed on anthrax, botulinum toxin, and radiological devices and a special study conducted on fissile materials. HHS has moved out promptly in addressing these threats, with contracts in place for first and second generation anthrax vaccines, and a pediatric formulation of

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potassium iodide. HHS is also in the acquisition process for botulinum antitoxin, anthrax therapeutics, and the next generation of smallpox vaccine, and has issued a number of Requests for Information (RFIs) for other medical countermeasures.

We are currently addressing the next tier of threats. Assessments are nearly complete for plague, tularemia, and chemical nerve agents, and an assessment of viral hemorrhagic fevers will be initiated in August. Based on the outcomes of these assessments, the Secretary of DHS may issue additional Material Threat Determinations.

Risk Assessments Across a Broader Range of Biological Threats

The preceding discussion dealt with threat assessments and near-term BioShield acquisitions of countermeasures against those CBRN agents widely agreed to be of greatest concern. As part of its responsibility in the President's National Biodefense Strategy, DHS is conducting a formal risk assessment of a much broader set of biological agents to help prioritize the nation's ongoing biodefense activities, including subsequent rounds of BioShield acquisitions. These risk assessments provide a systematic evaluation of the technical feasibility of a broad range of biological threats, the vulnerability of different portions of our society to those threats, and the resulting consequences of any such attacks.

The first such formal risk assessment is due in the January of 2006, with subsequent assessments due every two years. The scope, process, and timescale for this first assessment have been presented to and agreed to by the interagency Biodefense Policy Coordinating Committee co-chaired by the Homeland Security Council and the National Security Council. This assessment is addressing:

- All six category A agents from the Centers for Disease Control and Prevention (CDC) threat list;
- All 12 category B agents;
- Five representative category C agents; and
- A number of candidate drug-resistant and emerging agents.

Key outputs will include:

- A list of bio-threats prioritized by risk;
- A prioritized list of critical knowledge gaps that if closed should reduce risk assessment uncertainty and guide biodefense research and development; and
- A list of biodefense vulnerabilities that could be reduced by countermeasure development and acquisition.

This risk assessment is being conducted in partnership with the Intelligence Community, the HHS, the Department of Defense, the U.S. Department of Agriculture, the Environmental Protection Agency and others. Two advisory boards, one a Government Stakeholders Advisory Board and the other an Independent Risk Assessment Expert

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Review Board (academia, industry, and government), have been established to provide input and advice.

This and subsequent risk assessments will play a critical role in informing future biodefense programs across all agencies, including BioShield acquisitions and the longer-term medical R&D leading up to such acquisitions.

A Strategy for Addressing Emerging Threats

Much of the biodefense efforts to date have focused on protecting against attacks with bioterrorism agents that can be (or used to be) found in nature. However, rapid advances in biotechnology demand that we also consider the possibility and impact of emerging or engineered agents. e.g. modifications to organisms that increase their resistance to medical countermeasure or make them more difficult to detect. The President's *Biodefense for the 21st Century* assigns the HHS the lead in anticipating such future threats. The S&T Directorate is partnering with HHS and others in formulating and implementing a strategy for anticipating and responding to such threats.

Based on intelligence information, available literature and expert judgment, we have developed an informed estimate of the types of emerging threats that might be within the ability of a terrorist organization to develop over the near (1-3 years), mid (4-10 years), and longer-terms (10 yrs). We have also examined the impact of these threats on the four pillars of the National Biodefense Policy as articulated in Homeland Security Presidential Directive (HSPD)-10: Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery.

In this analysis, four elements stand out as essential to an effective defense against emerging threats:

- Threat, vulnerability and risk assessments to prioritize these threats in terms of the difficulty of their development and deployment, as well as their potential consequences;
- Surveillance and detection capabilities to rapidly detect and characterize engineered agents in environmental and clinical samples so as to provide timely guidance in the selection of the appropriate medical countermeasure;
- An expanded range of safe and effective medical countermeasures and an infrastructure to support rapid research, development, test, and evaluation (RDT&E) of new medical countermeasures; and
- Integrated concepts of operation (CONOPS) for the identification and response to emerging threats. In addition to conducting these assessments, DHS will continue to collaborate with HHS as it leads efforts to anticipate agents and to facilitate the availability of medical countermeasures.

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Scientific research to better inform these threat and risk assessments

The threat and risk assessments described above are performed with the best available information. However, there are large uncertainties, sometimes factors of ten to a hundred, in some of the key parameters and hence in the associated risks. One of the major functions of the threat and risk assessments is to identify these critical knowledge gaps, which can differ for different threat scenarios – in one case it can be the minimum amount of agent needed to infect a person; in another case it can be the time that such an agent remains viable (capable of causing an infection) in the air, food or water; and in a third it can be the effect of food processing or water treatment on the agent's viability. Conducting the laboratory experiments to close the critical knowledge gaps is a primary function of DHS's National Biodefense Analysis and Countermeasures Center (NBACC).

Congress has appropriated a total of $128M for design and construction of NBACC with the necessary biocontainment laboratory space and support infrastructure to conduct these and other experiments. NBACC will be built on the National Interagency Biodefense Campus (NIBC) at Ft. Detrick MD, where it is in close proximity to the DoD's United States Army Medical Research Institute for Infectious Diseases (USAMRIID), the NIH's Integrated Research Facility and the USDA's Foreign Disease-Weed Science Research Unit. NBACC is also collaborating with the Centers for Disease Control and Prevention to further address the critical knowledge gaps. The Record of Decision for NBACC's Final Environmental Impact Statement was signed in January 2005. Design of the facility began in March 2005, with construction scheduled to begin in FY 2006 and be complete by the fourth quarter of FY 2008.

Currently, interim capabilities for both NBACC's biological threat awareness and bioforensic analysis functions have been established with other government and private laboratories to allow vital work in these areas to occur during the NBACC facility's construction

CONCLUSION

In summary, the DHS Science and Technology Directorate's programs in threat and risk assessment play a critical role in prioritizing both near and longer-term BioShield research, development, and procurements for medical countermeasures. Throughout this process we work closely with our colleagues at HHS through a variety of interagency, bi-lateral, and informal scientist-to-scientist interactions so as to most effectively couple DHS expertise on the threat and risk with HHS expertise on human health to better protect our Nation.

This concludes my prepared statement. With the Committee's permission, I request my formal statement be submitted for the record. Mr. Chairman, Congressman Waxman, and Members of the Committee, I thank you for the opportunity to appear before you and I will be happy to answer any questions that you may have.